about 10% to about 100%.

REMARKS

Reconsideration of the present application, as amended, is respectfully requested.

I. STATUS OF THE CLAIMS

Claims 1-17 are pending in this application. Claims 1, 10, and 15 have been amended to more particularly point out that microcrytalline cellulose is excluded from the recited processing aid. Support for the above amendments can be found throughout the specification as originally filed, e.g., at page 12, lines 12-14. It is respectfully submitted that no new matter has been added by virtue of this amendment.

II. REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The Examiner rejected claims 1 and 10 under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, the Examiner rejected claims 1 and 10 under 35 U.S.C. § 112, second paragraph, on the grounds that the phrase "except for microcrystalline cellulose" was vague and indefinite".

In response, claims 1, 10 and 15 have been amended to replace the phrase "except for microcrytalline cellulose" with the phrase " wherein said processing aid is not microcrystalline cellulose".

The Examiner further rejected claim 10 on the grounds that the term "an" in claim 10, section B was vague and probably the result of a "typographical error".

In response, claim 10 has been amended to replace the term " an" with the term "a" in

section B of the claim.

In view of the actions taken, it is respectfully requested that the above rejections be withdrawn.

III. OBVIOUSNESS DOUBLE PATENTING REJECTION

The Examiner rejected claims 1-3, 10-12, 15 and 17 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10, 12, 19, and 24 of U.S. Patent No. 5,411,745. The Examiner stated that a timely filed Terminal Disclaimer may be deemed to overcome the rejection.

In response it is respectfully submitted that the Applicants will consider filing a terminal disclaimer upon indication that the claims are otherwise allowable.

IV. REJECTIONS UNDER 35 U.S.C. § 103

Claims 1-17 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,073,380 to Babu et al (hereinafter referred to as the Babu patent) in view of U.S. Patent No. 4,865,851 to James et al (hereinafter referred to as the James patent). According to the Examiner, the Babu patent teaches oral sustained release tablet formulations prepared by wet granulation, wherein povidine in water or alcohol water may be used as a granulating agent and mixed with a pharmaceutical agent and microcrystalline cellulose, and that the resulting granulate may be blended with additional ingredients such as dry powdered smooth enhancers, e.g. povidone and erosion promoters, e.g. pregelatinized starch and then compressed into tablets. The Examiner conceded that the Babu patent failed to teach maltodextrin as well as particle diameter. However, the Examiner took the position that it would been obvious to one skilled in the art to modify the composition of the Babu patent by adding the composition of the James

patent, and that the motivation to make this combination comes from "..a sustained release formulation with added benefits of suitable coating agent and the appropriate particle diameter would lead to successfully producing an multi layered formulation, which allows for various rates of dissolution of the active agent." Further, the Examiner asserted that the James patent teaches oral pharmaceutical compositions comprising cefuroxime axetil coated with an integral coating of a lipid or a mixture of lipids, as well as the preferred use of maltodextrin as a coating material and the use of other coating materials in its formulation such as pregelatinized maize starch, polyvinylpyrrolidone, lactose, talc etc. The Examiner also asserted that the James patent disclosed diameters below 1000 microns, and more particularly below 800 microns.

This rejection is respectfully traversed as it is respectfully submitted that one skilled in the art would not be motivated to combine the Babu reference and the James reference.

The Babu patent is directed to slow release compressed tablets, while the James patent is directed to pharmaceutical compositions comprising particles or granules delivered in an aqueous solution, suspension or swallowed as a dry product with water (col.5, lines 30-36). Accordingly, as these references are directed to distinct dosage forms, one skilled in the art would not have been motivated to combine the teachings of these references.

Even assuming arguendo that these reference that these references were properly combinable, one skilled in the art would still not arrive at the present invention based on a combination of these references.

The present invention is directed in part to methods for the preparation of powdered-layered inert beads prepared by coating the inert beads with a homogenous powder mixture comprising a drug and a processing aid.

In sharp contrast, the Babu patent describes an active agent mixed together with other inactive excipients in a wet granulation which is then dried, and additional excipients are subsequently blended with the granulation and compressed into tablets (See col. 3, lines 26-34). The Babu patent does not describe a method of coating inert beads with a homogeneous powder mixture comprising a therapeutically active agent and a processing aid.

The Examiner relies on the James reference to cure the deficiencies of the Babu reference. The James patent describes cefuroxime axetil in particulate form, the particulates being provided with integral coatings of a lipid or a mixture of lipids which are insoluble in water and which serve to mask the bitter taste of the drug. Accordingly, the James patent describes a drug coated with excipient and does not describe inert beads coated with a drug, let alone inert beads coated with a homogeneous powder mixture comprising a drug and a processing aid.

Therefore, even if these references were combined, one skilled in the art would not arrive at the presently claimed invention based upon these arguments at the very least.

In view of the above, it is respectfully submitted that the Examiner's rejections based on the Babu and James patents should be removed.

V. Conclusion

It is respectfully requested that claims 1- 17 as currently presented are in condition for allowance and favorable action is earnestly solicited.

According to currently recommended Patent Office policy, the Examiner is specifically authorized to contact the undersigned in the event that a telephone interview would advance the prosecution of the case.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: _____

Robert J. Paradiso
Reg. No. 41,240

Davidson, Davidson & Kappel, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018

U.S. Patent Application Serial No. 09/598,324

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

The claims have been amended as follows:

1. (Amended) A method for preparing powder-layered beads containing a therapeutically effective agent, comprising powder-layering inert beads having a diameter from about 0.1 mm to about 2.5 mm with a homogeneous powder mixture comprising a therapeutically active agent and a processing aid having a bulk density which is substantially similar to the bulk density of the therapeutically effective agent, wherein said processing aid is not microcrystalline cellulose [except for microcrystalline cellulose], until said beads achieve a weight gain of at least about 10% to about 100%.

10. (Amended) A method for preparing an oral dosage form of powder-layered beads containing a therapeutically effective agent, comprising

(A) identifying the bulk density of the therapeutically effective agent to be powder-layered;

(B) identifying a [an] processing aid in the form of a powder having a bulk density which is substantially similar to the bulk density of the therapeutically effective agent, wherein said processing aid is not microcrystalline cellulose [except for microcrystalline cellulose];

(C) admixing the therapeutically effective agent with said processing aid to form a homogeneous powder mixture; and

(D) powder-layering inert beads having a diameter from about 0.1 mm to about 2.5 mm with said homogeneous powder mixture until said beads achieve a weight gain of at least about 10% to about 100%.

15. (Amended) A method for preparing an oral dosage form of powder-layered beads containing a therapeutically effective agent having a bulk density from about 0.2 to about 0.8 g/ml, comprising

(A) identifying the bulk density of the therapeutically effective agent to be powder-layered;

(B) identifying a processing aid in the form of a powder having a bulk density from about 0.4 to about 0.9 g/ml which is substantially similar to the bulk density of the therapeutically effective agent, wherein said processing aid is not microcrystalline cellulose [except for microcrystalline cellulose] ;

(C) admixing the therapeutically effective agent with said processing aid to form a homogeneous powder mixture; and

(D) powder-layering inert beads having a diameter from about 0.1 mm to about 2.5 mm with said homogeneous powder mixture until said beads achieve a weight gain of at least about 10% to about 100%.